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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,285	11/13/2003	Wamis Singhatat	ZL 0195	9330

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LARGO, FL 33773

EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/712,285

Applicant(s)

SINGHATAT, WAMIS

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 8-11, 16-18, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claims 8, 16, and 26** the word "means" is preceded by the word(s) "further comprising" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The applicant should clarify the actual structure by which the deformed position or the suture locking position is held in place. Furthermore, within the claimed invention, it is unclear whether the deformed position is the same as the suture locking position because the examiner understands the deformed position to be a relative term. An open position can be considered deformed in comparison to a closed position, and vice versa. Hence, the applicant should be consistent with the terminology and clarify this matter.

Regarding **claims 10 and 11**, the limitation "the eyelet" has insufficient antecedent basis for this limitation in the claim. It is the examiner's understanding that the applicant is referring to the aperture as claimed in claim 1 when he or she uses the term eyelet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 13-16, 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yarnitsky et al. (US- 6287324).

Yarnitsky discloses a suture anchor for anchoring a suture to a body tissue:

Regarding **claim 1**, a distal body portion for securing the suture anchor in the body tissue (fig.4, 4); an aperture for receiving a portion of the suture (fig.4, 28); and a deformable body portion for deforming the aperture to compress and grip the suture (fig.4, 16).

Regarding **claim 2**, a proximal body portion having the aperture formed transversely there through (fig.4).

Regarding **claim 3**, the proximal body portion is deformable radially inwardly (fig.1).

Regarding **claim 4**, at least two elongated body members (fig.1,2,4, 16) forming sides of the aperture, at least one of the elongated body members being deformable radially inwardly to deform the aperture (as elongated members 16 are moved outwardly or inwardly, aperture changes conformation).

Regarding **claim 5**, at least one of the elongated members is hingedly attached to the distal body portion for radial inward hinged movement from a suture receiving position to a suture gripping position (fig.1).

Regarding **claims 6 and 21**, proximal body portion include at least one channel angling away from the aperture to receive the suture in a recessed protected position (when elongated members 16 are in the open position, inner side of 16 forms a channel angling away from the aperture).

Regarding **claim 8 and 16**, means for holding the deformable body portion in the deformed position (external rotational drive; col.5, lines 54-57; col.6, lines 31-33).

Regarding **claim 13**, the deformable body portion is configured to deform upon insertion into a hole formed in the body tissue (col.5, lines 58-61; col.6, lines 61-66).

Regarding **claims 14 and 20**, deformable body portion has a generally elliptical shape before it is deformed (when members 16 are in open position, deformable body portion 28 has a generally elliptical shape) and a generally circular shape when it is deformed to grip the suture (when 16 is in closed position, deformable portion 28 forms a circle; fig. 4).

Yarnitsky et al. discloses a unitary suture anchor for securing a suture to a bone without tying a knot comprising:

Regarding **claim 15**, a distal body portion for securing the suture anchor to the bone (fig.4, 4); a proximal body portion for securing the suture to the suture anchor (fig.4, 19), the proximal body portion comprising: a pair of elongated and relatively movable first body members (fig.4, 16), at least one of the first body members being

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hingedly connected to the distal body portion, the first body members being relatively movable between a suture receiving position (fig.1, 3) and a suture locking position (fig.1, 2)); a transverse suture receiving aperture interposed between the first body members for receiving the suture therein when the first body members are in the suture receiving position (fig.4, 28), the aperture being deformed to grip the suture when the first body members are in the suture locking position (aperture deforms from a wide elliptical conformation when 16 are spread apart to a smaller circular conformation when members 16 are brought closer together to a closed conformation).

Yarnitsky et al. discloses a method for securing a suture to a body tissue, the method comprising:

Regarding **claim 22**, providing a suture anchor having a distal body portion for securing the suture anchor in the body tissue (fig.4, 4), an aperture for receiving a portion of the suture (fig.4, 28), and a deformable body portion for deforming the aperture to compress and grip the suture (fig.4, 16); inserting a portion of the suture through the aperture (suture 10 is situated in 28); deforming the deformable body portion to deform the aperture and grip the suture (fig.1 depicts changing the aperture); and inserting the suture anchor into the body tissue (col.6, lines 43-44).

Regarding **claim 23**, the step of inserting the anchor into the body tissue simultaneously causes the deformable body portion to deform the aperture (col.5, lines 58-64).

Regarding **claim 24**, the step of inserting the anchor into the body tissue comprises inserting the anchor into a hole formed in a bone and insertion of the suture

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anchor into the hole causes the deformable body portion to deform radially inwardly (referring to col.6, lines 31-66, after the external rotational drive is removed, the suture anchor disclosed by Yarnitsky will automatically transform to the open position. It is inherent that the deeper the suture anchor is placed in the bone, the radial compressive forces will bring the first body portions (16) inward. Hence, suture anchor disclosed by Yarnitsky is capable of radially inward deformation because of the flexible nature of the first body portions (16) while insertion into the bone).

Regarding **claim 25**, tensioning the suture while inserting the anchor (col.6, lines 27-30).

Regarding **claim 26**, activating the means for holding the deformable body portion in the deformed position (col.5, lines 61-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yarnitsky et al. (US- 6287324) in view of DiPoto et al. (US-5258016).

Yarnitsky discloses the invention substantially as claimed above. Yarnitsky does not disclose the distal body portion including annular rings for gripping the body tissue.

However, DiPoto et al. teaches ridges (fig.8, 62). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the suture anchor disclosed by Yarnitsky to incorporate annular rings or ridges as taught by DiPoto. Such a modification would provide the apparent advantage of holding the anchor in place (col.5, lines 60-64).

Claims 9-11, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarnitsky et al. (US- 6287324) in view of Gogolewski et al. (US-5236431).

Regarding **claim 9**, Yarnitsky discloses the invention substantially as claimed above. Yarnitsky fails to disclose a means for holding comprising a mechanism including a projection on one portion of the suture anchor and a recess for receiving the projection on another portion of the suture anchor, the projection locking in the recess to maintain the aperture in the deformed condition when the aperture is deformed.

However, Gogolewski teaches a projection and a recess for maintaining the aperture in the deformed condition (fig. 13A). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the elongated flexible members arms (16) disclosed by Yarnitsky to include a projection and recess as taught by Gogolewski in order to maintain a deformed condition. Such a modification would have the apparent advantage of not requiring an external means for maintaining a certain conformation.

Regarding **claims 10 and 11**, Yarnitsky discloses the invention substantially as claimed above, but fails to disclose the eyelet to receive at least two suture ends arranged vertically or horizontally within the eyelet.

However, Gogolewski teaches a variety of eyelets that can receive at least two suture ends vertically (fig. 1, 3A, 4A, 5A, 6A) or horizontally (fig. 2A, 7A) within the eyelet. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the aperture (fig.4, 28) as disclosed by Yarnitsky to include various arrangement of apertures as taught by Gogolewski. Such a modification would provide the advantage of having sutures engage with the tissue or bone in various conformations, allowing for better attachment.

Regarding **claim 19**, Yarnitsky discloses the invention substantially as claimed above, but fails to disclose that the suture anchor is formed from a bioabsorbable material. However, Gogolewski teaches a reabsorbable fixation device. Therefore, it is old and well known in the art and would be obvious to person of ordinary skill in the art at the time of the invention to modify the suture anchor disclosed by Yarnitsky to made bioabsorbable as taught by Gogolewski. Also see patent US- 5814070 (col.4, lines 26-29). Such a modification would prevent further surgeries to remove the suture anchor.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarnitsky et al. (US- 6287324) in view of Schwartz et al. (US- 6293961).

Regarding **claims 17 and 18**, Yarnitsky discloses the invention substantially as claimed above. Yarnitsky fails to disclose a transverse body member extending from each of the first body members, the transverse body members being in relative sliding contact, the transverse body members and first body members forming a ratchet and pawl mechanism in which a portion of each transverse body member snaps over a

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portion of the opposing first body member to lock the first body members in the suture locking position.

However, Schwartz teaches a snap lock mechanism (fig. 9). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the first body members (16) disclosed by Yarnitsky to include a snap lock mechanism as taught by Schwartz. Hence, when the first body members (16) are slideably brought closer together, the snap lock would engage the two first body members as taught by Schwartz. Such a modification would allow for an easy locking means to retain the suture anchor in a locked or closed position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12/22/06.